

memorandum

DATE March 31, 1995

REPLY TO

ATTN OF Office of Environmental Policy and Assistance (EH-413): Bascietto:6-7919

SUBJECT Baseline Risk Assessment: Toxicity and Exposure Assessment and Risk Characterization

TO: Distribution

The purpose of this memorandum is to provide Department of Energy (DOE) Program Offices and Field Organizations with a copy of an environmental guidance document entitled: "*CERCLA Baseline Risk Assessment Manual for Toxicity and Exposure Assessment and Risk Characterization*." This document is directed primarily to DOE and DOE contractor personnel responsible for planning, managing and communicating risk assessment information for environmental restoration projects performed under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). Notwithstanding, the attached document provides information to all personnel interested in gaining both-an understanding of selected baseline risk assessment topics and a perspective on the evolving nature of risk assessment guidance in the CERCLA program.

Over recent years the U.S. Environmental Protection Agency (EPA) has developed a considerable body of guidance about developing baseline risk assessments for uncontrolled hazardous waste sites. But the manner in which EPA's guidance is interpreted and applied can have a great impact on the risk estimates obtained and, in turn, on the remedial option selected to reduce those risks. In general, lower baseline risk estimates should necessitate less costly remedial options than will higher risks. This document was written to (1) guide project personnel through the process of interpreting EPA guidance and (2) help project personnel to discuss EPA guidance with regulators, decision makers, and stakeholder as it relates to conditions at a particular DOE environmental restoration site.

This environmental guidance document provides detailed insight into the science policy issues underlying the CERCLA baseline risk assessment process as it is implemented today by EPA, and serves as a continuing reference work that can be consulted for information on the baseline risk assessment process in the DOE environmental restoration program. To the extent possible, given the evolving nature of risk assessment guidance in general, the document attempts to summarize the Agency's up-to-date national guidance to EPA regional offices on selected CERCLA baseline risk assessment topics, and, through an historical perspective, examines how certain guidance has changed over time. This perspective facilitates a discussion of the pros, cons, weaknesses, uncertainties, and policy areas where more than one interpretation may be acceptable for each of the topics covered. Additionally, the document identifies reference materials for risk analysts who may desire a more in-depth understanding of a particular topic. A primary intent of this guidance is to assist in facilitating a thoughtful discourse on baseline risk assessment issues among the Department's environmental restoration project managers and their regulators.

A earlier draft of the attached document, entitled: "CERCLA Baseline Risk Assessment Issues" was circulated within DOE headquarters field elements for review and comment. EH-413 endeavored to ensure that the DOE perspective, and in particular the environmental restoration program CERCLA experience, has been accurately represented. To that end, the draft manual has been improved through the incorporation of the comments received from a select group of DOE headquarters and Field Organization representatives. The comments received by EH-413 reflected substantial DOE experience in planning, managing and communicating CERCLA baseline risk assessments.

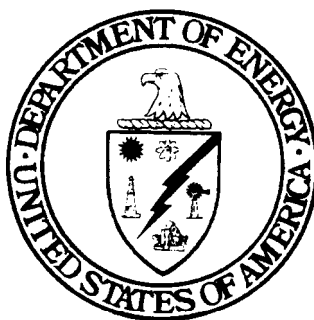
Questions concerning the CERCLA baseline risk assessment guidance topics covered, or other comments on the information contained in the attached document, may be directed to John Bascietto of my staff by calling (202) 586-7917, fax to (202) 586-3915 and electronic mail at Internet address john.bascietto@hq.doe.gov.

A handwritten signature in black ink, appearing to read "T. Traceski", is positioned above the printed name.

Thomas T. Traceski
Director, RCRA/CERCLA Division
Office of Environmental Policy and Assistance

Attachment

CERCLA BASELINE RISK ASSESSMENT
Reference Manual
for
Toxicity & Exposure Assessment and Risk Characterization



MARCH 1995

Prepared by

U.S. DEPARTMENT OF ENERGY
OFFICE OF ENVIRONMENTAL POLICY & ASSISTANCE
(formerly the Office of Environmental Guidance)
RCRA/CERCLA DIVISION
(EH-413)
Washington, D.C.

Technical support by

Energetic, Inc.
Columbia, MD

ACKNOWLEDGEMENTS

This document was developed by the Department of Energy (DOE) Office of Environmental Policy and Assistance, RCRA/CERCLA Division (EH-413), with technical support provided by Energetic, Inc. Argonne National Laboratory provided a technical review of Chapter 6, "Radiation Risk Assessment." The following individuals provided technical review and invaluable perspectives on DOE experience with regulator oversight of CERCLA baseline risk assessments:

Steve Golian, Office of Environmental Activities, EM-22
Mildred Ierre, Environmental Restoration Div., Oak Ridge Operations Office
Kelly Kelkenberg, Regulatory Integration Div., EM-431
Steve Miller, Office of General Counsel, GC-51
Tish O'Connor, Office of Environmental Activities, EM-22
Melanie Pearson, Environmental Compliance Div., EH-411
Bruce Thatcher, Environmental Restoration Div., Rocky Flats Field Office
Wade Whittaker, Environmental Compliance Div., Savannah River Operations Office

Table of Contents

Chapter 1: Introduction	1-1
1.1 Background	1-1
1.2 Baseline Risk Assessment: an Overview	1-2
1.2.1 Introduction	1-2
1.2.2 Data Collection and Evaluation	1-2
1.2.3 Exposure Assessment	1-4
1.2.4 Toxicity Assessment	1-5
1.2.5 Risk Characterization	1-7
1.3 How to Use This Document	1-11
1.4 References	1-12
 Chapter 2: Guide to Issue Discussions	 2-1
2.1 Introduction	2-1
2.2 Issues Pertaining to Exposure Assessment	2-1
2.2.1 Exposure and Dose	2-3
Issue 1: Exposure/Dose Terminology	2-3
Issue 2: Exposure/Dose Calculations	2-4
Regulator Dialogue	2-4
2.2.2 Estimation of Average and Upper End Risk	2-4
Issue 1: Risk Descriptors	2-4
Issue 2: Professional Judgement	2-4
Regulator Dialogue	2-5
2.2.3 Radiation Risk Assessment	2-5
Issue 1: Exposure Calculations	2-5
Issue 2: Radionuclide Progeny	2-5
Regulator Dialogue	2-5
2.2.4 Institutional Controls	2-5
Issue 1: Evaluation of Institutional Controls	2-5
Issue 2: Exposure Scenario Development	2-6
Regulator Dialogue	2-6
2.2.5 Site-Specific Data Versus Default Factors	2-6



Issue 1: Use of Site-Specific Data	2-6
Issue 2: Use of Default Factors	2-6
Regulator Dialogue	2-6
2.2.6 Data Gaps, Uncertainty, and Professional Judgement	2-7
Issue 1: Sources of Uncertainty	2-7
Issue 2: Impact of Data Gaps on Risk Estimate	2-7
Issue 3: Means to Address Uncertainties	2-7
Regulator Dialogue	2-7
2.3 Issues Pertaining to Toxicity Assessment	2-7
2.3.1 Noncancer Health Endpoints	2-8
Issue 1: Alternative Toxicity Values	2-8
Issue 2: Alternative Toxicity Study Requirements	2-8
Regulator Dialogue	2-9
2.3.2 Data Gaps, Uncertainty, and Professional Judgement	2-9
Issue 1: Sources of Uncertainty	2-9
Issue 2: Impact of Uncertainty on Risk Estimates	2-9
Issue 3: Means to Address Uncertainty	2-9
Regulator Dialogue	2-9
2.4 Issues Pertaining to Risk Characterization	2-9
2.4.1 Chemical Mixtures	2-10
Issue 1: Dose Additivity	2-10
Issue 2: Impacts of Summing HQs and Slope Factors	2-10
Regulator Dialogue	2-11
2.4.2 Data Gaps, Uncertainty, and Professional Judgement	2-11
Issue 1: Sources of Uncertainty	2-11
Issue 2: Impact of Uncertainty on Risk Estimates	2-11
Issue 3: Means to Address Uncertainty	2-11
Regulator Dialogue	2-12
2.5 Conclusion	2-12
2.6 References	2-24
 Chapter 3: Exposure and Dose	 3-1
3.1 Introduction	3-1
3.2 Discussion of Exposure and Dose in Statutes, Regulations, and Guidelines	3-1



3.2.1 Statutes and Regulations	3-1
3.2.2 Guidelines	3-2
Guidelines for Estimating Exposures	3-2
Superfund Public Health Evaluation Manual (SPHEM)	3-2
Superfund Exposure Assessment Manual (SEAM)	3-3
The Exposure Factors Handbook (EFH)	3-3
EPA Region I Supplemental Guidance	3-3
Risk Assessment Guidance for Superfund, Volume I (RAGS)	3-3
Exposure Assessment Methods Handbook (EAMH)	3-4
Dermal Exposure Assessment: Principles and Applications (DEAPA)	3-5
Guidelines for Exposure Assessment	3-5
3.3 Issues and Regulator Dialogue	3-6
3.3.1 Exposure/Dose Issues	3-6
Semantic Ambiguities in Exposure/Dose Terminology	3-6
Inconsistent Exposure/Dose Calculations	3-7
3.3.2 Regulator Dialogue	3-8
3.4 References	3-9
 Chapter 4: Estimation of Average and Upper-End Risk	4-1
4.1 Introduction	4-1
4.2 Discussion of Estimation of Average and Upper-End Risk in Statutes, Regulations, and Guidelines	4-2
4.2.1 Statutes and Regulations	4-2
Superfund Public Health Evaluation Manual (SPHEM)	4-2
Superfund Exposure Assessment Manual (SEAM)	4-3
4.2.3 Overcoming Initial Guidance Conceptual Framework Limitations	4-4
EPA Regional Guidance	4-5
EPA Headquarters Guidance	4-6
4.2.4 Further Concerns with Superfund Exposure Assessment Guideline Conceptual Framework	4-7
Creation of an EPA Risk Assessment Intra-Agency Group in March of 1990	4-7
Creation of EPA Superfund 30-Day Task Force	4-7
4.2.5 Addressing Exposure Assessment Guideline Conceptual Framework Concerns	4-7
Guidance for Risk Assessment	4-7

Supplemental Guidance to RAGS: Calculating the Concentration Term	4-8
Guidelines for Exposure Assessment	4-8
An SAB Report: Superfund Site Health Risk Assessment Guidelines	4-9
4.3 Issues and Regulator Dialogue	4-9
4.3.1 Average and Upper-End Risk Issues	4-9
Concept of Reasonableness	4-11
Use of Professional Judgement	4-12
4.3.2 Regulator Dialogue	4-12
4.4 References	4-13
Chapter 5: Chemical Mixtures	5-1
5.1 Introduction	5-1
5.2 Discussion of Chemical Mixtures in EPA Guidelines	5-2
5.2.1 Guidelines for the Health Risk Assessment of Chemical Mixtures	5-2
5.2.2 Guidelines for Estimating Exposures	5-3
5.2.3 Superfund Public Health Evaluation Manual (SPHEM)	5-3
5.2.4 Risk Assessment Guidance for Superfund, Volume I (RAGS)	5-4
5.2.5 Guidelines for Exposure Assessment	5-6
5.2.6 An SAB Report: Superfund Site Health Risk Assessment Guidelines	5-6
5.3 Issues and Regulator Dialogue	5-7
5.3.1 Chemical Mixture Issues	5-7
Dose Additivity Can Lead to Errors If Synergistic or Antagonistic Interactions Occur	5-8
Summing HQs Treats All RfDs Equally	5-9
Cancer-causing Substances are Treated Equally When Summing Slope Factors	5-10
Upper 95th Percentile Estimates of Potency Are Not Strictly Additive	5-10
5.3.2 Regulator Dialogue	5-10
5.4 References	5-11
Chapter 6: Radiation Risk Assessment	6-1
6.1 Introduction	6-1
6.2 Discussion of Radiation Risk Assessment in Statutes and Regulations	6-2
6.2.1 Statutory and Regulatory Radiation Risk Assessment Framework	6-2



6.3 Exposure	6-2
6.3.1 Exposure Pathways	6-2
6.3.2 Exposure Assessment	6-3
6.3.3 Radiation Dosimetry	6-3
6.4 Toxicity	6-4
6.4.1 Toxicity Assessment	6-4
6.4.2 Radiation Health Effects in Humans	6-6
6.5 Risk	6-6
6.5.1 Cancer Risks	6-6
6.5.2 Genetic Risks	6-6
6.5.3 Developmental Risks	6-7
6.5.4 Radiation Risk Calculation Methodology	6-7
Internal Exposure	6-7
External Exposure	6-8
6.6 Radiation Units Conversion	6-9
6.6.1 SI Units	6-9
6.6.2 Conversion Factors	6-9
6.7 Regulator Dialogue	6-10
6.8 References	6-10
 Chapter 7: Noncancer Health Endpoints	 7-1
7.1 Introduction	7-1
7.2 Discussion of Noncancer Health Endpoints in Statutes, Regulations, and Guidelines	7-1
7.2.1 Statutory and Regulatory Noncancer Toxicity Assessment Framework	7-1
7.2.2 General Guidance for Noncancer Toxicity Assessment	7-2
Superfund Public Health Evaluation Manual (SPHEM)	7-2
Risk Assessment Guidance for Superfund (RAGS), Volume 1: Human Health Evaluation Manual	7-2
7.2.3 Guidelines for Reproductive Toxicity Assessments	7-4
Proposed Guidelines for Assessing Female Reproductive Risk	7-5
Proposed Guidelines for Assessing Male Reproductive Risk	7-6
7.2.4 Guidelines for Developmental Toxicity Assessments	7-7
Guidelines for the Health Assessment of Suspect Developmental Toxicants	7-7
Guidelines for Developmental Toxicity Risk Assessment	7-8



7.3 Issues and Regulator Dialogue	7-10
7.3.1 Noncancer Health Endpoint Issues	7-10
Alternative Toxicity Values Can Be Presented in the Risk Assessment	7-11
Appropriate Study Design	7-11
Selection and Interpretation of Toxicity Endpoints	7-12
7.3.2 Regulator Dialogue	7-12
7.4 References	7-13
 Chapter 8: Institutional Controls in Baseline Risk Assessments	8-1
8.1 Introduction	8-1
8.2 Discussion of Institutional Controls in Statutes, Regulations, and Guidelines	8-1
8.2.1 Statutes	8-1
8.2.2 Regulations	8-1
8.2.3 Guidelines	8-2
8.3 Issues and Regulator Dialogue	8-3
8.3.1 Institutional Controls Issues	8-3
Evaluation of Institutional Controls	8-3
Institutional Controls in Exposure Scenario Development	8-3
Institutional Controls in Land Use Determination	8-4
8.3.2 Regulator Dialogue	8-5
8.4 References	8-5
 Chapter 9: Site-Specific Data Versus Default Factors	9-1
9.1 Introduction	9-1
9.2 Discussion of Site-Specific Data Versus Default Factors in Statutes, Regulations, and Guidelines	9-1
9.2.1 Statutes and Regulations	9-1
9.2.2 Guidelines	9-1
Guidelines for Estimating Exposures	9-1
Superfund Public Health Evaluation Manual (SPHEM)	9-2
Superfund Exposure Assessment Manual (SEAM)	9-3
Risk Assessment Guidance for Superfund, Volume I (RAGS)	9-3
The Exposure Factors Handbook (EFH)	9-4
Research to Improve Health Risk Assessments (RIHRA)	9-4

Supplemental Guidance to RAGS: EPA Region I Guidance	9-5
Supplemental Guidance to RAGS: Standard Default Exposure Factors	9-5
EPA Superfund 30-Day Task Force	9-5
Exposure Assessment Methods Handbook (EAMH)	9-6
An SAB Report: Superfund Site Health Risk Assessment Guidelines	9-6
9.3 Issues and Regulator Dialogue	9-6
9.3.1 Site-Specific Data versus Default Factors Issues	9-6
Limited Site-Specific Data Warrants the Use of Conservative Default Factors	9-7
Site-Specific Data are Preferred to Standard Default Factors	9-8
9.3.2 Regulator Dialogue	9-8
9.4 References	9-9
Chapter 10: Data Gaps, Uncertainty, and Professional Judgement	10-1
10.1 Introduction	10-1
10.2 Discussion of Data Gaps, Uncertainty, and Professional Judgement in Statutes, Regulations and Guidelines	10-2
10.2.1 Statutes and Regulations	10-2
10.2.2 Guidelines	10-2
Guidelines for Estimating Exposures	10-2
Superfund Public Health Evaluation Manual (SPHEM)	10-3
Superfund Exposure Assessment Manual (SEAM)	10-3
EPA Region I Supplemental Guidance	10-4
The Exposure Factors Handbook (EFH)	10-4
Risk Assessment Guidance for Superfund, Volume I (RAGS)	10-5
Guidance for Data Useability in Risk Assessment (GDURA)	10-6
Supplemental Guidance to RAGS: Standard Default Exposure Factors	10-7
Exposure Assessment Methods Handbook (EAMH)	10-7
Guidance for Risk Assessment	10-8
Supplemental Guidance to RAGS: Calculating the Concentration Term	10-8
Guidelines for Exposure Assessment	10-9
10.3 Issues and Regulator Dialogue	10-10
10.3.1 Data Gaps, Uncertainty, and Professional Judgement Issues	10-10
Exposure Assumptions and Toxicity Values are Great Sources of Uncertainty ..	10-10
Uncertainties Tend to Overestimate Risk	10-11

Limited Prescribed Protocols to Address Uncertainty	10-13
Use of Professional Judgement	10-13
10.3.2 Regulator Dialogue	10-13
10.4 References	10-14

Appendix A: Annotated Bibliography

Appendix B: Land Use in the CERCLA Remedy Selection Process

Appendix C: EPA Risk Characterization Program



List of Figures

Figure 1.1:	RI/FS Process	1-3
Figure 2.1:	Correspondence Between BRA Components and Chapters in This Guidance	2-2
Figure 2.2:	Issues Pertaining to Exposure Assessment	2-3
Figure 2.3:	Issues Pertaining to Toxicity Assessment	2-8
Figure 2.4:	Issues Pertaining to Risk Characterization	2-10
Figure 7.1	Benchmark Dose Approach	7-10

List of Tables

Table 1.1:	EPA Weight-of-Evidence Classification System for Carcinogenicity	1-7
Table 2.1:	Guide to Issues and Source Documents	2-13
Table 10.1:	Typical Sources of Uncertainty in CERCLA Risk Assessments	10-11

